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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

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09/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/037,718	MCGINNIS ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *3/22/2010, 6/25/2010,and 6/28/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91,92,105,212 and 236-307* is/are pending in the application.

4a) Of the above claim(s) *236-307* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-92, 105, and 212* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed 03/22/2010 have been entered.

Applicant's amendments filed 06/25/2010 have been entered.

Applicant's amendments filed 06/28/2010 have been entered.

Request For Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/22/2010 has been entered.

Election by Original Presentation

Newly submitted claims 236-307 filed 06/28/2010 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Applicant has admitted for the record that the newly presented claims are product by process claims; see Remarks filed 6/25/2010. Applicant's assertion that the newly presented claims cannot be restricted are not persuasive for the following reasons.

Newly submitted claims 236-307 are directed to a method for making a composition for obtaining genotype data. Previously examined claims 91-92, 105, and 212 are drawn to composition for obtaining genotype data. The newly submitted claims would have been restricted from the previously examined claims as follows:

Group I: Claims 91-92, 105, and 212 drawn to composition for obtaining genotype data, classified in class 702, subclass 019.

Group II: Claims 236-307 drawn to a process for making a composition for obtaining genotype data, classified in class 702, subclass 019.

The inventions are distinct and divergent, each from the other because of the following reasons:

The inventions of Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the method as claimed could be used to make many other species of covering markers with different spatial distances and map regions, for example. Similarly, the claimed composition comprising a set of oligonucleotides could be made by a different method that requires other types of CL-F maps related to different species and/or population of creatures and requires a different chromosomal, for example. Thus, the search for the two groups together would present an undue search burden as they are directed to a composition (i.e. product) and a method that are generally distinct and separate.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable

product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. Failure to do so may result in no rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 236-307 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

Claims 91-92, 105, 212, and 236-307 are currently pending.

Claims 1-90, 93-104, 106-211, 213-235 are cancelled.

Claims 236-307 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 91-92, 105, and 212 are under consideration.

Specification

The objection to the specification is withdrawn in view of the amended specification filed 03/22/2010.

Priority

Applicant's arguments, filed 3/22/2010, that the instant application should be granted priority (e.g. to documents PCT/US99/04376 and 09/947,768) in view of applicant's response on pp. 52-57 of the Amendment/Response of March 10, 2009, have been fully considered but are not persuasive for the following reasons.

Claim 91 requires the limitations "wherein the CL-F region is a segment-subrange,...whereby the length of the segment is greater than or equal to about 47 million base pairs, wherein the subrange of the segment-subrange includes the least common allele frequency 0.1, whereby there are at least about 24 covering markers with least common allele frequencies less than or equal to 0.3 that are distributed within the segment with a density of at least about 1 marker every two million base pairs.

Applicant's response filed March 10, 2009, regarding priority documents PCT/US99/04376, 60/076102, and 09/947,768, applicant states [see p.57] "*that the number at least about 24 covering markers in the whereby clause necessarily follows from dividing the length of human chromosome 21 (about 47 million base pairs) by the density (about 1 marker every 2 million base pairs). This yields the number about 23.5. Since there is no such thing as 1/2 of a marker, the number is rounded up to 24.*" In response, merely stating that one new essential limitation recited in the claim "necessarily follows" from another limitation of the claim is not sufficient; i.e. a disclosure of yellow microarrays and blue microarrays does not provide support for green microarrays. Furthermore, applicant is introducing new limitations in this reasoning that have nothing to do with the claims (e.g. rounding a number up to a whole number). For at least these reasons, the prior-filed disclosures do not provide support for each

claim limitation as at least one essential element lacks adequate written description. See MPEP 2163.

As stated in the last Office action, a review of the entire specification shows nothing more than a general discussion of conventional techniques for choosing a set of markers for scanning chromosomal regions; see e.g. pages 4 and 5. The specification also generally describes principles and concepts for using a set of oligonucleotides, technology for genotyping of individuals, and theoretical linkage studies and power analysis for bi-allelic covering markers; see e.g. '718 application pages 22-22, 32, 35, 36, 37, and 39. However, the instant specification does not provide any evidence that applicant was actually in possession of the claimed set of oligonucleotide compositions (e.g. a disclosure of specific SEQ ID numbers) selected for a utility to determine genotype information as in claim 91. Therefore neither the instant application nor the prior-filed applications provide support (written description) for the underlined limitations. This application is granted the benefit of priority to its filing date of 01/04/2002.

Withdrawn Rejections

The rejection of claims 91-93, 105, and 212 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn after further consideration and in view of applicant's arguments filed 06/25/2010, that undue experimentation would not have been required in view of the guidance provided in the specification, e.g. pages 44-47.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 91-92, 105, and 212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claim 91 are also rejected due to said dependency.

The following rejections are newly applied.

Regarding claim 91: The claim is directed to a composition. However, the claim recites "wherein" phrases such as "wherein the set of oligonucleotides is selected for the set's utility to determine genotype data; and "wherein the group of covering markers is chosen so that....is N covered to within [x,y]; see at least claim 91, lines 4-9. A compound cannot comprise method steps. The above limitations appear to be method steps (e.g. selecting oligonucleotides and choosing covering markers). Therefore, as the claimed invention is directed to a composition of oligonucleotides, it is unclear whether applicant intends these "wherein" phrases to be further limitations of the claimed composition and, if so, what structural limitations of the claimed composition are intended in each case.

Regarding claims 92 and 105: These claims recite limitations of the CL-F region, covering markers, and allele frequencies. However, as the claimed invention is directed to a composition of oligonucleotides, it is unclear what structural limitations of the claimed

composition are intended by further limitations of the CL-F region, covering markers, and allele frequencies.

Regarding claim 212: The claim recites a utility to obtain genotype data or sample allele frequency data by generating a signal, wherein the signal is generated by the products of a polymerase chain reaction when oligonucleotides of the composition hybridize with one or more complementary alleles of one or more of the covering markers. These limitations appear to be intended use limitations and method steps (e.g. generating signals). It is unclear whether applicant intends these limitations to be further limitations of said composition and if so, what structural limitations of the claimed composition are intended.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 91, 92, 105, and 212 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained.

The claims, as currently written, are drawn to a set of oligonucleotides, being complementary to a set of covering markers chosen so that a CL-F region is N-covered to within specific [x,y] two-dimensional distances and wherein the CL-F region that is N-covered to within [x,y], wherein x is less than or equal to 1 million base pairs and y is less than or equal to 0.2, and wherein N is less than maximal, and whereby the number and distribution of known markers in the neighborhood of the CL-F region make it possible for N to be a greater value, the covering markers and CL-F region being for a species of creatures, and whereby the CL-F region is a segment-subrange that is greater than or equal to the length of the human chromosome 21, as in claim 91. A review of the entire specification shows nothing more than a general discussion of conventional techniques for choosing a set of markers for scanning chromosomal regions; see e.g. pages 4 and 5. The specification also generally describes principles and concepts for using a set of oligonucleotides, technology for genotyping of individuals, and theoretical linkage studies and power analysis for bi-allelic covering markers; see e.g. pages 22-22, 32, 35, 36, 37, and 39. However, the specification does not provide any evidence that applicant was actually in possession of the claimed set of oligonucleotide compositions (e.g. a disclosure of specific SEQ ID numbers) selected for a utility to determine genotype information as in claim 91. Therefore one of ordinary skill in the art would have reasonable doubt that the applicant was actually in possession of such oligonucleotide compositions obtained in the way the instant claims describe at the time the application was filed.

Response to Arguments

Applicant's arguments filed 03/22/2010 have been fully considered but are not persuasive for the following reasons.

In response to applicant's arguments; see pages 30-32 in Remarks filed 03/22/2010, that the claims meet the written description requirement since they are "product-by-process" claims, the instant claims are directed to composition for use in obtaining genotype data. A review of the entire specification only shows a description of principles and concept. There is no indication or disclosure that applicant was actually in possession of an oligonucleotide composition selected for utility to determine genotype data as described in claim 91, for example, and with all those functional limitations for any particular chromosome 21, as in clam 91. In response to applicant's arguments that point to *Fiers v. Revel*, this case has an entirely different fact pattern from those of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 91, 92, 105, and 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinnis et al. (WO 99/43858; International Publication Date: 02 September 1999; IDS filed 09/22/2008), in view of Kruglyak et al. (Am. J. Hum. Genetic., 1995, 57:439-454; IDS filed 04/04/2002), and in view of Cohen (EP 0 892 068; Publication Date: 20 January 1999; IDS filed 5/20/2008).

The following rejection is newly applied.

In view of the confusing manner in which the claims have been written and the unclarity with regards to how the limitations of the claimed covering markers and CL-F region further limit the claimed composition (see 112 2nd rejection above), the instant claims are broadly interpreted as being directed to a composition comprising a set of oligonucleotides being complementary to a group of two or more bi-allelic covering markers.

McGinnis teaches a set of oligonucleotides complementary to a group of two or more bi-allelic covering markers of the same species within specific CL-F distances; see at least p.9, p.14-16, p.31, p.35, Example 1S, p.36, and Ref. Claims 70-88, which meets the claim language for a composition comprising a set of oligonucleotides being complementary to a group of two or more bi-allelic covering markers.

McGinnis does not teach limitations directed to covering markers that systematically cover a CL-F region that is N-covered to within [x,y], wherein x is less than or equal to 1 million base pairs and y is less than or equal to 0.2, or whereby the CL-F region is a segment-subrange that is greater than or equal to the length of the human chromosome 21, or whereby the length of the segment is greater than or equal to about 47 million base pairs, wherein the subrange of the segment-subrange includes the least common allele frequency 0.1, or whereby there are at least about 24 covering markers with least common allele frequencies less than or equal to 0.3 that are distributed within the segment with a density of at least about 1 marker every two million base pairs, as in claim 91.

McGinnis does not teach limitations of the CL-F region, covering markers, and allele frequencies, as in claims 92 and 105.

McGinnis does not teach a utility to obtain genotype data or sample allele frequency data by generating a signal, wherein the signal is generated by the products of a polymerase chain reaction when oligonucleotides of the composition hybridize with one or more complementary alleles of one or more of the covering markers, as in claim 212.

Kruglyak teaches the use of bi-allelic markers in linkage studies. Kruglyak shows genotyped markers spaced along a chromosome with known allelic frequencies; see at least

pages 440-443, Fig. 1, Fig. 2. Markers with the highest heterozygosity have the highest information content; see Fig. 3, Fig. 4. The methods and compositions of Kruglyak are useful for studying the effects of marker density, polymorphism, and parental information content in an automated fashion, see Summary.

Cohen teaches the use of bi-allelic markers in PCR-based technologies; see at least page 4, lines 1-20, and shows the use of such markers in PCR for purposes of amplification; see page 8 and Figures 1 and 2.

McGinnis, Kruglyak, and Cohen do not specifically teach the limitations recited in claims 91, 92, 105, and 212, directed to limitations of the claimed covering markers and CL-F (chromosomal location and least allele frequency) region. However, these limitations are interpreted as non-functional descriptive subject matter because they do not clearly result in structural limitations of the claimed set of oligonucleotides. MPEP 2112.01 states that where the only difference between a prior art product and a claimed product is non-functional subject matter, the content of the non-functional subject matter will not distinguish the claimed product from the prior art. *In re Ngai,* 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983). Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have provided the oligonucleotide composition of claim 91, wherein only nonfunctional descriptive material is additionally present in the instant claims which do not distinguish the claimed oligonucleotides from the oligonucleotides and uses thereof, as taught by McGinnis, Kruglyak, and Cohen, as above, in view of *In re Ngai* and *In re Gulack.*

Response to Arguments

Applicant's remarks filed 06/28/2010 that undue experimentation would not have been required in view of the guidance provided in the specification, e.g. pages 44-47, are persuasive. The rejection claims 91-93, 105, and 212 are rejected under 35 U.S.C. 112, first paragraph, is therefore withdrawn. However, new grounds of rejections have been applied, as set forth above.

Applicant's arguments filed 03/22/2010 and 06/25/2010 have been fully considered but are moot in view of the new grounds of rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

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/PW/

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